



FORM PTO-1449

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Atty Docket No.

P1989R1

Serial No.

10/697,142

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Semba Charles P.

Filing Date

30 Oct 2003

Group

Not Assigned

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

TU	70	Abbas, A. E., et al., "Intracoronary Fibrin-Specific Thrombolytic Infusion Facilitates Percutaneous Recanalization of Chronic Total Occlusion" <u>Journal of the American College of Cardiology</u> 46(5):793-798 (2005)
	71	Cairolì O.M., "Practical Application: Using Tissue Plasminogen Activator Overnight in Catheter Clearance on Tunnel Catheters Used for Hemodialysis" <u>Proceedings of the 22nd Annual Conference on Dialysis</u> 22(Suppl. 1):S56 (Mar 2002)
	72	Daeihagh, P., et al., "Efficacy of Tissue Plasminogen Activator Administration on Patency of Hemodialysis Access Catheters" <u>American Journal of Kidney Diseases</u> 36(1):75-79 (Jul 2000)
	73	Dowling, K., et al., "The Use of Tissue Plasminogen Activator Infusion to Re-establish Function of Tunneled Hemodialysis Catheters" <u>Nephrology Nursing Journal</u> 31(2):199-200 (March-April 2004)
	74	Eyrich, H., et al., "Alteplase versus urokinase in restoring blood flow in hemodialysis-catheter thrombosis" <u>Am. J. Health-Syst. Pharm.</u> 59:1437-1440 (Aug 1, 2002)
	75	Gibson, S. P., et al., "Five Years Experience with the Quinton Permcath for Vascular Access" <u>Nephrology Dialysis Transplantation</u> 6:269-274 (1991)
	76	Habowski, S.R. et al., "Use of Tissue Plasminogen Activator (t-PA) for Hemodialysis Catheter Malfunction" <u>J. Am. Soc. Nephrol.</u> 11:185A (2000)
	77	Hammes, M. S., et al., "Intraluminal Alteplase (t-PA) Is an Effective Means To Treat Occluded Hemodialysis (HD) Catheters" <u>J. Am. Soc. Nephrol.</u> 12:290A (2001)
	78	Little, M. A., et al., "A Longitudinal Study of the Repeated Use of Alteplase as Therapy for Tunneled Hemodialysis Catheter Dysfunction" <u>American Journal of Kidney Diseases</u> 39(1):86-91 (Jan 2002)
	79	Moss, A. H., et al., "Use of a Silicone Catheter With a Dacron Cuff for Dialysis Short-Term Vascular Access" <u>American Journal of Kidney Diseases</u> XII(6):492-498 (Dec 1988)
	80	National Kidney Foundation, "K/DOQI Clinical Practice Guidelines for Vascular Access, 2000" <u>Am J Kidney Dis</u> 37:S137-S181 (Suppl 1 2001)
	81	O'Mara, N.B., et al., "tPA for Central Vein Dialysis Catheter Patency" <u>J. Am. Soc. Nephrol.</u> 11:292A
	82	Refino, C. J., et al., "A Variant of Tissue Plasminogen Activator (T103N, N117Q, KHRR 296-299 AAAA) With a Decreased Plasma Clearance Rate is Substantially More Potent Than Activase rt-PA in a Rabbit Thrombolysis Model" <u>Thrombosis and Haemostasis, Abstracts edition</u> 69(6):841 (1993)
	83	Roberts, Nicole E. et al., "Outpatient Use of Alteplase (t-PA) in De-Clotting Dialysis Catheters" <u>J. Am. Soc. Nephrol</u> 11:195A (2000)
	84	Spry, L. A., et al., "Low-Dose tPA for Hemodialysis Catheter Clearance" <u>Dialysis &amp; Transplantation</u> 30(1):10-13 (Jan 2001)
	85	Suhocki, P. V., et al., "Silastic Cuffed Catheters for Hemodialysis Vascular Access: Thrombolytic and Mechanical Correction of Malfunction" <u>American Journal of Kidney Diseases</u> 28(3):379-386 (Sep 1996)
	86	U.S. Renal Data System, <u>USRDS 2005 Annual Data Report: Atlas of End-Stage Renal Disease in the United States</u> (National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases), Bethesda, MD (2005)
	87	Zacharias, J.M., et al., "Alteplase Versus Urokinase for Occluded Hemodialysis Catheters" <u>The Annals of Pharmacotherapy</u> 37:27-33 (Jan 2003)

Examiner

/Thane Underdahl/

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## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
TU ↓	1	2001/0021811A1	13.09.01	Yock			
	2	5,612,029	18.03.97	Bennett et al.			
	3	5,849,736	15.12.98	Wityak et al.			
	4	5,865,178	02.02.99	Yock			
	5	6,346,517	12.02.02	Wong et al			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
TU ↓	6	WO 00/53264	14.09.00	PCT				
	7	WO 95/14683	01.06.95	PCT				
	8	WO 98/028326	02.07.98	PCT				

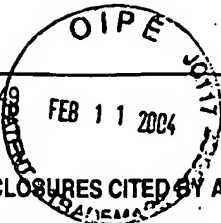
## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

TU ↓	9	Allie et al., "Novel Combination Thrombolytic Therapy in Limb Salvage: Mechanical Thrombectomy (Rheolytic Thrombectomy with Angiojet) and Chemical Thrombolysis (Tenecteplase) "Power-Pulse Spray" Technique" <u>Am. J. Cardiol.</u> 90:108H (2002)						
	10	Allie et al., "Tenecteplase in Peripheral Thrombolysis: Initial Safety and Feasibility Experience, abstract 48 of Society of Intervention Radiology" pps. S17 (Mar 2003)						
	11	Arepally et al., "Weight-based rt-PA Thrombolysis Protocol for Acute Native Arterial and Bypass Graft Occlusions" <u>J. Vasc. Interv. Radiol.</u> 13:45-50 (2002)						
	12	Assent-2 investigators, "Single-bolus tenecteplase compared with front-loaded alteplase in acute myocardial infarction: the ASSENT-2 double-blind randomised trial. Assessment of the Safety and Efficacy of a New Thrombolytic Investigators" <u>Lancet</u> 354:716-722 (1999)						
	13	Azmi-Ghadimi et al., "Use of Intraventricular Tissue Plasminogen Activator and Guglielmi Detachable Coiling for the Acute Treatment of Casted Ventricles from Cerebral Aneurysm Hemorrhage: Two Technical Case Reports" <u>Neurosurgery</u> 50:421-424 (2002)						
	14	Benedict et al., "New variant of human tissue plasminogen activator (TPA) with enhanced efficacy and lower incidence of bleeding compared with recombinant human TPA" <u>Circulation</u> 92(10):3032-3040 (1995)						
	15	Bookstein and Bookstein, "Augmented Experimental Pulse-Spray Thrombolysis with Tissue Plasminogen Activator, Enabling Dose Reduction by One or More Orders of Magnitude" <u>J. Vasc. Interv. Radiol.</u> 11:299-303 (2000)						
	16	Bookstein and Bookstein, "Plasminogen-enriched Pulse-Spray Thrombolysis with tPA: Further Developments" <u>J. Vasc. Interv. Radiol.</u> 11:1353-1362 (2000)						
	17	Burkart et al., "Thrombolysis of Acute Peripheral Arterial and Venous Occlusions with Tenecteplase and Eptifibatide: A Pilot Study" <u>J. Vasc. Interv. Radiol.</u> 14:729-733 (2003)						
	18	Burkart et al., "Thrombolysis of Occluded Peripheral Arteries and Veins with Tenecteplase: A Pilot Study" <u>J. Vasc. Interv. Radiol.</u> 13:1099-1102 (2002)						
	19	Calis et al., "Bioactivity of cryopreserved alteplase solutions" <u>Am. J. Health Syst. Pharm.</u> 56:2056-2057 (1999)						
	20	Castaneda et al., "Catheter-directed Thrombolysis in Deep Venous Thrombosis with Use of Reteplase: Immediate Results and Complications from a Pilot Study" <u>J. Vasc. Interv. Radiol.</u> 13:577-580 (2002)						
	21	"Cathflo Activase. Full Prescribing information" 2002 Physicians Desk Reference, Montvale, NJ:Thomas Medical Economics Co. (2002)						

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TU	22	Chang et al., "Daily Catheter-directed Single Dosing of t-PA in Treatment of Acute Deep Venous Thrombosis of the Lower Extremity" <u>J. Vasc. Interv. Radiol.</u> 12:247-252 (2001)
	23	Collen, D. et al., "Comparative thrombolytic properties of tissue-type plasminogen activator and of a plasminogen activator inhibitor-1-resistant glycosylation variant, in a combined arterial and venous thrombosis model in the dog" <u>Thrombosis and Haemostasis</u> 72(1):98-104 (1994)
	24	Cornelius et al., "Adsorption of proteins from infant and adult plasma to biomaterial surfaces" <u>J. Biomed. Mater. Res.</u> 15:622-632 (2000)
	25	Davidian et al., "Initial Results of Reteplase in the Treatment of Acute Lower Extremity Arterial Occlusions" <u>J. Vasc. Interv. Radiol.</u> 11:289-294 (2000)
	26	Dawson et al., "Plasminogen Mutants Activated by Thrombin" <u>Journal of Biological Chemistry</u> 269:15989-15992 (1994)
	27	Decrinis et al., "A simplified procedure for intra-arterial thrombolysis with tissue-type plasminogen activator in peripheral arterial occlusive disease: primary and long-term results" <u>European Heart Journal</u> 14:297-305 (1993)
	28	Drescher et al., "Initial Experience with the Combination of Reteplase and Abciximab for Thrombolytic Therapy in Peripheral Arterial Occlusive Disease: A Pilot Study" <u>J. Vasc. Interv. Radiol.</u> 13:37-43 (2002)
	29	Elsharaway and Elzayat, "Early Results of Thrombolysis vs Anticoagulation in Iliofemoral Venous Thrombosis.. A Randomized Clinical Trial" <u>Eur. J. Vasc. Endovasc. Surg.</u> 24:209-214 (2002)
	30	Findlay et al., "Lysis of intraventricular hematoma with tissue plasminogen activator" <u>J. Neurosurg.</u> 74:803-807 (1991)
	31	Graul et al. <u>Xemilifiban; Drugs of the future</u> 22:508-517 (1997)
	32	Hara, T. et al., "DX-9065a, a New Synthetic, Potent Anticoagulant and Selective Inhibitor for Factor Xa" <u>Thrombosis and Haemostasis</u> 71(3):314-319 (1994)
	33	Hofmann et al., "GP1Ib-IIIa Receptor Inhibitors: What the Interventional Radiologist Needs to Know" <u>Cardiovasc. Interv. Radiol.</u> 24:361-367 (2001)
	34	Kaiser, "Thrombin and factor Xa inhibitors" <u>Drugs of the Future</u> 23:423-436 (1998)
	35	Kawasaki et al., "Effect of a Synthetic Factor Xa Inhibitor, YM-60828, on Blood Vessel Patency in Combination with a Thrombolytic Agent and on Blood Loss from the Operation Site in a Rat Model of Arterial Thrombosis" <u>Thromb. Haemost.</u> 79:859-864 (1998)
	36	Keyt et al., "A Faster-Acting and More Potent Form of Tissue Plasminogen Activator." <u>Proc. Natl. Acad. Sci. USA</u> 91:3670-3674 (1994)
	37	LeBlang et al., "Low-Dose Urokinase Regimen for the Treatment of Lower Extremity Arterial and Graft Occlusions: Experience in 132 cases" <u>J. Vasc. Interv. Radiol.</u> 3:475-483 (1992)
	38	McNamara and Fischer, "Thrombolysis of Peripheral Arterial and Graft Occlusions: Improved Results Using High-Dose Urokinase" <u>Am. J. Radiol.</u> 144:769-775 (1985)
	39	McNamara et al., "Bleeding Associated With Intrathrombus Infusions of r-tPA for Peripheral Arterial and Venous Occlusion" <u>Am. J. Cardiol.</u> 84:37P (1999)
	40	Mewissen et al., "Catheter-directed Thrombolysis for Lower Extremity Deep Venous Thrombosis: Report of a National Multicenter Registry" <u>Radiology</u> 211:39-49 (1999)
	41	Nehme et al., "Tenecteplase for the Lyse and Wait Technique in Recanalization of Thrombosed PTFE Hemodialysis Grafts" <u>J. Vasc. Interv. Radiol.</u> 13:S109 (2002)

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TU	42	Ouriel et al., "A Comparison of Recombinant Urokinase with Vascular Surgery as Initial Treatment for Acute Arterial Occlusion of the Legs" <u>New England J. of Medicine</u> 16:1105-1111 (1998)
	43	Ouriel et al., "Complications Associated with the Use of Urokinase and Recombinant Tissue Plasminogen Activator for Catheter-directed Peripheral Arterial and Venous Thrombolysis" <u>J. Vasc. Interv. Radiol.</u> 11:295-298 (2000)
	44	Ouriel et al., "Reteplase in the Treatment of Peripheral Arterial and Venous Occlusions: A Pilot Study" <u>J. Vasc. Interv. Radiol.</u> 11:849-854 (2000)
	45	Patel et al., "SCVIR Reporting Standards for the Treatment of Acute Limb Ischemia with Use of Transluminal Removal of Arterial Thrombus" <u>J. Vasc. Interv. Radiol.</u> 12:559-570 (2001)
	46	Razavi et al., "Initial Clinical Results of Tenecteplase (TNK) in Catheter-Directed Thrombolytic Therapy" <u>J. Endovasc. Ther.</u> 9:593-598 (2002)
	47	Razavi et al., "Initial Clinical Results of Tenecteplase (TNK) in Catheter-Directed Thrombolytic Therapy" <u>J. Vasc. Interv. Radiol.</u> 13(2):S11 (Feb 2002)
	48	Refino et al., "A Variant of t-PA (T103N, KHRR 296-299 AAAA) that, by Bolus, Has Increased Potency and Decreased Systemic Activation of Plasminogen" <u>Thromb. Haemost.</u> 70:313-319 (1993)
	49	"Retavase. Full prescribing information" <u>2002 Physicians Desk Reference</u> , Montvale, NJ:Thomas Medical Economics Co. (2002)
	50	Ricotta et al., "Use and limitations of thrombolytic therapy in the treatment of peripheral arterial ischemia: Results of a multi-institutional questionnaire" <u>J. Vasc. Surg.</u> 6:45-50 (1987)
	51	Scarborough et al., "Eptifibatide" <u>Drugs of the future</u> 23:585-590 (1998)
	52	Semba and Dake, "Iliofemoral Deep Venous Thrombosis: Aggressive Therapy with Catheter-directed Thrombolysis" <u>Radiology</u> 191:487-494 (1994)
	53	Semba et al., "Alteplase and Tenecteplase: Applications in the Peripheral Circulation" <u>Tech. Vasc. Interv. Radiol.</u> 4:99-106 (2001)
	54	Semba et al., "Alteplase as an Alternative to Urokinase" <u>J. Vasc. Interv. Radiol.</u> 11:279-287 (2000)
	55	Semba et al., "Alteplase Stability and Bioactivity after Thrombolysis-Facilitated Rheolytic or High-Speed Maceration Thrombectomy" <u>J. Vasc. Interv. Radiol.</u> 13 2 (Part 2):S76 (Feb 2002)
	56	Semba et al., "Tenecteplase (TNK): Protein Stability and Bioactivity of Thawed or Diluted Solutions Used in Peripheral Thrombolysis" <u>J. Vasc. Interv. Radiol.</u> 13(2):Part 2: S75 (Feb 2002)
	57	Semba et al., "Tenecteplase: Stability and Bioactivity of Thawed or Diluted Solutions Used in Peripheral Thrombolysis" <u>J. Vasc. Interv. Radiol.</u> 14:475-479 (2003)
	58	Semba et al., "Thrombolytic Therapy with Use of Alteplase (rt-PA) in Peripheral Arterial Occlusive Disease: Review of the Clinical Literature" <u>J. Vasc. Interv. Radiol.</u> 11:149-161 (2000)
	59	Shortell et al., "Safety and efficacy of limited-dose tissue plasminogen activator in acute vascular occlusion" <u>J. Vasc. Surg.</u> 34:854-859 (2001)
	60	The STILE Investigators, "Results of a Prospective Randomized Trial Evaluating Surgery Versus Thrombolysis for Ischemia of the Lower Extremity. The STILE trial" <u>Ann. Surg.</u> 220:251-268 (1994)
↓	61	"STREPTASE. Full prescribing information" <u>Physicians Desk Reference</u> , Montvale, NJ:Thomas Medical Economics Co. (2002)

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